UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,943	02/22/2002	Loren J. Field	7037-458	6536

7590 03/07/2006

Kenneth A. Gandy
Woodard, Emhardt, Naughton, Moriarty & McNett
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, IN 46204-5137

EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/080,943	FIELD ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-17,23-27,34 and 37-50* is/are pending in the application.

4a) Of the above claim(s) *34 and 37-43* is/are withdrawn from consideration.

5)☒ Claim(s) 23 is/are allowed.

6)☒ Claim(s) *11-17,24-27 and 44-50* is/are rejected.

7)☒ Claim(s) *40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/22/2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 2, 2205 has been entered.

DETAILED ACTION

This application filed February 22, 2002, is a continuation of PCT/US00/23161 with the international filing date of August 23, 2000, which claims benefit to US provisional application 60/150,266 filed August 23, 1999.

Applicants amendment filed December 2, 2005 has been received and entered. Claims 1-10, 18-22, 28-33, 35-36 have been canceled. Claims 49 and 50 have been amended. Claims 11-17, 23-27, 34, 37-50 are pending.

Election/Restrictions

Applicant's election of Group VII, claims 15-17, in the reply filed on June 4, 2004 was acknowledged. In the first action, the Examiner determined it would not be an undue burden to examine both groups VI and V , and the restriction requirement between groups V and VI was withdrawn.

As noted in the first office action, Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement of each of the different inventions, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Further, as noted in the previous office action, the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.1 16; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1 .104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the

restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Claims 11-17, 23-27, 34, 37-50 are pending. Claims 18-22, 28-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 11-17, 23-27, 44-50 are currently under examination as they are drawn to a vector encoding p193 and a host cell comprising a vector.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 2, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. 37 CFR 1.821(d) states:

"[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application.

In this case, the specification contains sequence not defined by a SEQ ID NO; For example, page 12, line 28, contains a protein sequence. It is appreciated that it is a subsequence of SEQ ID NO 4, however it is presented as a sequence itself. Similarly, Figure 1(b) and figure 2(b) contain a protein sequence.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-17, 24-27, 44-50 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants summarize the teaching of the specification and argue that it would not constitute an undue burden in view of the specification to test various constructs to see if the anti-apoptotic activity. See Applicants amendment, bridging pages 6-7. Applicants arguments have been fully considered, but not found persuasive.

Adequate written description is not whether one can try various alterations of an invention encompassed by the claim to see if it meets the functional requirements of a claim, rather given the guidance of the specification, would the artisan appreciate that applicant was in possession of a reasonable breadth of the claim. In this case, the simple question would be, given SEQ ID NO2 and any other sequence, would one of skill in the art be able to know the second sequence met the functional limitations required by written description. In this case, it appears that Applicants arguments acknowledge that testing would be required. Examiner would not contest that the technology exists to test the function of an encoded protein, and the present specification provides enough guidance to test the apoptotic function of a protein. However, the requirement of testing provides evidence that disclosure fails to adequately describe the product as broadly claimed.

Again, the specification does teach the isolation and characterization of two specific sequences that encodes a protein that has a molecular weight of 193 kDa, however the specification fails to provide any clear guidance to any other sequences encompassed by the claim. Moreover, the guidelines for written description set forth that both a structure and function must be provided to address the requirement of 35 USC 112, first paragraph. Even

when a function is recited, as in dependent claim 17, the claimed invention as a whole is not adequately described because the disclosure fails to teach the essential or critical elements of the claimed invention, in particular the sequences other than SEQ ID NOs that have any apoptiotic function. Moreover, there are no specific methods set forth in the present disclosure for obtaining such a breadth of sequences. As note in the prior office action, Applicants have claimed a nucleic acid sequence encoding a p193 protein, however the specification fails to describe the relevant identifying characteristics of any of the nucleic acid sequences of a sufficient number of sequences which can be used in the instantly claimed method. The skilled artisan cannot envision all the possible variant nucleic acid sequences encompassed by the claims, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Again, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Therefore, for the reasons above and of record, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-17 and 23-27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendments to the claims and Applicants' arguments have addressed the rejections of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-17, 24-27, 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Nomura *et al.* (KIAA0076-IDS ref) as evidenced by Nomura *et al.* (DNA Research 1, 223-229 (1994)).

It is noted that "identity" is defined in the specification to mean a calculation made by using advanced BLAST program 2.0.8 (bridging pages 12-13). Given this definition and the ability of altering any parameter of the BLAST program, effectively any sequence would anticipate the sequences based on identity as instantly claimed. Further, the claims as written encompass "**an** amino acid sequence...to the sequence of SEQ ID NO:" thus would be interpreted to encompass fragments of p193. This is further supported by the explicit embodiment that the breadth of alterations encompasses fragments in the recitation of "the protein is a truncation mutant" (claim 48).

Nomura *et al.* teach KIAA0076, which encodes the human equivalent to p193 instantly disclosed. A sequence search indicates that the protein and nucleic acid that encodes the protein shares significant homology with SEQ ID NO: 2 and 4. Importantly, because of the breadth of

the claim regarding "identity" and the limitation that encompasses a fragment, the portions of the sequence that are identical clearly anticipate the breadth of the claimed invention.

Conclusion

Claim 23 is allowed because the prior art of record fails to teach or make obvious the specific sequences of SEQ ID NO: 2 or 4. As noted previously all of the claims are free of the art of record because the art fails to teach an isolated nucleic acid sequence encoding a p193 protein, and more specifically that set forth in SEQ ID NOs: 2-4. Further, the post filing art of Pasumarthi *et al.* and of Tsai *et al.* demonstrate that the function of the p193 protein is in the apoptotic pathway consistent with that disclosed in the instant specification. Though free of the art of record, the remaining claims are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach